FDA 510(k) Premarket Notification

K090138 MOBILECARE MONITOR, MODEL 2100

CLEARED

Apr 24, 2009
93 days to decision

K090138 · Product code: **KMI** · General Hospital
Source: https://www.510kdatabase.net/k090138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Bed Patient (KMI)
Date received	Jan 21, 2009
Decision date	Apr 24, 2009
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aframe Digital, Inc.**
Location	Mosely, VA, US
Contact	DARREN REEVES
510(k) history	2 submissions · 2 cleared · 2009-2012